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March 16, 2021

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VIA ECF & EMAIL

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Hon. Thomas I. Vanaskie (Ret.)

Special Master

Stevens & Lee

1500 Market St., East Tower, Suite 1800

Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***
Case No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Pursuant to Special Master Order No. 7, Plaintiffs write to provide a status report on the parties' efforts to resolve the ongoing Hetero discovery issues. As Your Honor is aware, the parties have engaged in numerous meet and confers in an attempt to resolve the ongoing, severe, and substantive deficiencies in Hetero's production, most recently today, March 16, 2021. While some issues have been addressed, significant issues remain unresolved and as of today, Hetero was not able to provide more concrete information in response to Plaintiffs' most recent correspondence despite the fact that Hetero has consulted with its ESI vendor and client on a continuous basis, which is a cause for concern in that we would have expected the issues to be pinned down and resolved by now. As a result, the depositions scheduled for this week were postponed again with

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no new date proposed since Plaintiffs still have no estimate as to when Hetero's production will be brought up to date.

As Plaintiffs stated in their March 9, 2021 letter to Your Honor, the materiality of the documents and information at issue (i.e., central quality control protocols and manuals, disclosure of applications and databases containing testing and other data and information, communications with regard to key protocols and the revisions thereof), and the slow pace of Hetero's actions, is on the threshold of requiring significant measures. These materials and information are central to the proof of the claims, have already caused depositions to be delayed, and Plaintiffs reserve the right to request litigation sanctions including an order finding liability.

Violations of the ESI Protocol

Plaintiffs wrote to Hetero on February 5, 2021, to discuss deficiencies in Hetero's production including violations of the Electronic Discovery Protocol filed June 19, 2019 (Document 127). This includes Hetero's Production Index, which is still not compliant with Section III, Paragraph I of the Electronic Discovery Protocol. Pursuant to Section III, Paragraph I, "Each production shall also contain a Production Index, which shall be updated with each production, setting forth (1) dates, (2) Bates number range, (3) source(s) (e.g., custodians, database) of the materials contained in each production volume, (4) whether the production was a replacement production, and (5) the date of withdrawal of protected designation and replacement with no protected designation for applicable Bates ranges, if applicable." The descriptions provided by Hetero fail to comply with this provision because Hetero's Custodial productions are not listed by Bates range and all Custodians are listed together. Other issues with the productions include insufficient metadata, such as documents that lack metadata for the "Created" and

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“Modified” dates, non-compliant formats for Custodian fields, which should list Custodians as “LASTNAME, FIRSTNAME, MIDDLENAME”, missing Author and Duplicate Custodian fields, and an inordinate number of documents listed with the Custodian “Hetero”.

While some of the metadata deficiencies have been addressed, many remain unresolved. During the meet and confer process with Hetero, Plaintiffs learned that Hetero was also producing documents under the generic, catch-all custodian “Hetero” instead of properly identifying the source of documents. This practice of simply dumping documents into a nonspecific Custodian with no indication of the actual source of the documents is in clear violation of the Electronic Discovery Protocol, and makes it impossible to trace documents to their sources. Hetero indicated that an overlay file has now been produced to remedy the issue of the generic “Hetero” custodian as well as other metadata deficiencies, but Plaintiffs have not yet confirmed this is the case as the production was just made.

Cast of Characters

On February 24, 2021, Hetero produced a “Cast of Characters” that Plaintiffs deemed to be incomplete due to missing titles and email addresses. Plaintiffs immediately alerted Hetero that the Cast of Characters was insufficient. Hetero advised Plaintiffs today, several weeks later, that they had not yet obtained all of the necessary information but did produce another version of the Cast of Characters with some additional information.

Missing Documents

During the review process, Plaintiffs identified several documents that have not been produced by Hetero and are critical to the depositions of 30(b)(6) witnesses. Specifically, Hetero has not produced all versions of the Standard Operating Procedures, Quality Systems Manual,

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Core Procedures, Site Master Files, Master SOP Indexes, Audit Reports and other documents relating to Hetero's adherence to the cGMP process. As of the most recent Hetero production, which was produced today, Hetero still has failed to produce all versions of the majority of the documents requested by Plaintiffs despite the fact that in most instances, Plaintiffs specifically identified for Hetero which versions were missing, to the best of Plaintiffs' ability. Plaintiffs have also not been able to locate documents, correspondence, or emails discussing the documents listed above, which seems impossible as many of these documents were revised in the aftermath of the revelation of the NDMA contamination. In addition, during review Plaintiffs identified several SOPs and quality documents where Annexures have not been produced. Hetero indicated that they would look into these issues and confirmed today that they are still not in a position to produce the outstanding Standard Operating Procedures and related quality documents.

Databases, Software and Applications

Plaintiffs have repeatedly requested that Hetero provide a list of all databases, software, and applications used to maintain relevant documents and information, and to confirm that all databases, software and applications were properly analyzed, and that all relevant data was produced. Hetero at first could not confirm this information. However, during the parties' meet and confer on March 11, 2021, Hetero indicated that the data was already produced and that details and more specific information about the production would be provided. Plaintiffs have yet to receive this additional information and Hetero advised Plaintiffs today that they were still preparing a response to this request.

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Document Production Issues

On February 16, 2021 and March 8, 2021, Plaintiffs identified several documents that were produced incorrectly with missing pages or with conflicting metadata. Hetero advised that they are still consulting with their ESI vendor regarding these issues and offered a potential explanation that Plaintiffs are currently investigating. The documents that were identified by Plaintiffs are below:

- a. HLL163283
 - i. This document should have at least 9 pages. Only one page was produced.
- b. HLL179202
 - i. This document should have at least 161 pages, yet only page three was scanned.
- c. HLL175512-HLL175566
 - i. Document should have 58 pages. Only 55 pages were produced.
- d. HLL183565
 - i. Cover page for CAPA document referencing an enclosure with NMBA results for Losartan; no enclosure was provided.
- e. HLL183566
 - i. Cover page for CAPA document referencing R&D evaluation report for Valsartan and Aripiprazole; no evaluation report provided.
- f. HLL183564
 - i. Cover page for CAPA document referencing an enclosure entitled "Notification Copy to Agency on NMBA results" but no enclosure is provided.

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g. HLL183561

- i. Cover page for CAPA document referencing an enclosure entitled "Updated List of Valsartan Batches on Hold" but no enclosure is provided.

h. HLL219568-HLL219570

- i. This document has missing pages. For example, it begins with "28. Acetone" which means there are pages containing information from pages 1 through 27 that were not produced or scanned.

i. HLL163400-HLL163405

- i. Document should have 181 pages. Only the first six pages were produced.

j. HLL124147-HLL124194

- i. Document begins on page 6 of 53. The first five pages are missing.

k. HLL210671-HLL210676

- i. Document should have twelve pages. Missing pages 2, 4, 6, 8, 10, and 12. should have twelve pages. Missing pages 2, 4, 6, 8, 10, and 12.

l. HLL219996-HLL220041

- i. HLL220004 is the beginning of a five-page document. Only three pages produced.

m. HLL178438-HLL178446

- i. This document should have at least 253 pages (see HLL178446). Only nine pages produced.

n. HLL220524-HLL220571

- i. HLL220528 is the beginning of a five-page document. Only three pages were produced.

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o. HLL163294-HLL163296

- i. This document should have at least 344 pages. Only three pages were produced.

p. HLL163386-HLL163388

- i. This document should have five pages. Only three pages were produced.

q. HLL203865-HLL203887

- i. HLL203876 begins what is possibly a seven-page document based on the page numbers at the bottom. However, HLL203876 starts on page 2. Page 1 is missing. Unknown if other pages are missing after page 7.

r. HLL175567-HLL175605

- i. This document should have at least 398 pages. 39 pages have been produced.

s. HLL212275-HLL212353

- i. This document is missing multiple pages.
- ii. HLL212318 -This is a three-page document. Pages 1 and 3 are missing.
- iii. HLL212320 - this is a four-page document. Pages 1 and 3 are missing.
- iv. HLL212323 - This is a four-page document. Pages 1 and 3 are missing.
- v. HLL212325 - This is a four-page document. Pages 2 and 4 are missing.
- vi. HLL212327 - This is a 26-page document. Pages 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, and 26 are missing.

t. HLL163300

- i. This document should have at least 17 pages. Only page 2 has been provided.

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u. HLL215708-HLL215710

- i. This document is missing several pages. It begins on page 14, then skips to page 18, then skips to page 20.

v. HLL219859-HLL219863

- i. This document should have at least 43 pages. Only the first five pages have been produced.

w. HLL209485-HLL209510

- i. The first page of this document says page 1 of 21. The second page of this document says page 2 of 26.

x. HLL212634-HLL212643

- i. HLL212638 begins a test procedure document for Irbesartan that is supposed to have 10 pages. Only 2 pages have been produced.

y. HLL212246-HLL212252

- i. Multiple missing pages. For example, HLL212246 is page 1 of 2, but page 2 is not provided.
- ii. HLL212247 starts on page 16 (see bottom of page). Therefore, there are 15 pages prior that are missing.
- iii. HLL212250 is page 19 of a document. HLL212251 is page 21. Therefore, page 20 is missing.
- iv. HLL212252 is page 31 of a document. Pages 22 through 30 are missing.

z. HLL221375-HLL221382

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- i. This document is missing multiple pages. It begins on page 1 of 11; then skips to pages 17, 18, and 19; then skips to pages 21 and 22; then skips to pages 25 and 26.

aa. HLL163308-HLL163311

- i. This document should have 241 pages. Only four pages have been produced.

bb. HLL183562

- i. This document (Inspectional Observations: Attachments for Corrective Actions) should also have an enclosure entitled "Spike purge studies report for Valsartan and Losartan Potassium for the possibility of residual nitrite in sodium azide raw material." No enclosure is provided.

cc. HLL01235065 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Unit Name: HLL-I, Department: Engineering". The document also shows an effective date of 9/12/20. Are there prior or subsequent versions?

dd. . HLL01235069 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Unit Name: HLL-I; Department: Production". The document also shows an effective date of 9/2/22. Are there prior versions?

ee. HLL01235076 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Unit Code: HHL-I Department: Microbiology".

ff. HLL01235079 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Department Quality Control". Are there prior or subsequent versions?

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gg. HLL01235147 - Metadata shows document created on 2/19/21 but it was signed 10/10/11.

The parties have engaged in an extensive meet and confer process that has now spanned over a month and significant issues still remain. Hetero indicated today that additional productions would be made shortly and Plaintiffs will await those productions to assess whether the deficiencies will have been resolved. Given the lack of progress in resolution of significant issues and the ongoing prejudice, Plaintiffs are concerned and expect that by the end of the month conference a clear picture will exist as to whether these many issues will have been solved.

Thank you for your consideration.

Respectfully,



ADAM M. SLATER